

Message Text

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SUBJECT: TRADE FACILITATION COMMITTEE CASE--CORDIS-DOW

1. SUMMARY: COMMERCE (USDOC) FORWARDING NEW CASE FOR TFC CONSIDERATION SOONEST CONCERNING RECENT CHANGE IN JAPANESE GOVERNMENT REIMBURSEMENT OF DIALYSIS SERVICES WHICH DISCRIMINATES AGAINST THE USE OF SHORT-TERM DIALYZERS, WHICH ARE SUPPLIED TO THE JAPANESE MARKET PRIMARILY BY A U.S. EXPORTER, CORDIS-DOW. END SUMMARY

2. CORDIS-DOW CORP., UNDER COVER OF A LETTER TO USDOC OF APRIL 17 SUBMITTED A BRIEF (LETTER WITH BRIEF AND OTHER UNCLASSIFIED

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RELEVANT MATERIAL BEING POUCHED TO EMBASSY) CONCERNING THE DISCRIMINATORY EFFECT OF A BASIC CHANGE IN THE MINISTRY OF HEALTH AND WELFARE'S DIALYSIS FUNDING PROGRAM, MADE EFFECTIVE FEBRUARY 1, 1978, WITH ALMOST NO ADVANCE NOTIFICATION OR PUBLIC HEARINGS INVOLVING DOCTORS, PATIENTS, OR SUPPLIERS OF PRODUCTS.

3. TEXT OF TFC CASE ON BEHALF OF CORDIS-DOW TO BE PRESENTED TO JAPANESE OFFICIALS IN TFC AS FOLLOWS: BEGIN TEXT

A. SUMMARY OF CASE: RECENT CHANGE BY JAPANESE MINISTRY OF HEALTH AND WELFARE (MHW) IN DIALYSIS REIMBURSEMENT PROGRAM

UNDER JAPANESE NATIONAL HEALTH INSURANCE DISCRIMINATES AGAINST THE USE OF SHORT-TERM DIALYZERS, WHICH ARE SUPPLIED TO THE JAPANESE MARKET PRIMARILY BY A U.S. EXPORTER, CORDIS-DOW (C-D).

B. FACTS OF THE CASE:

(1) IN 1971 C-D INTRODUCED ON THE WORLD MARKET A HIGH-TECHNOLOGY, HIGH-COST, LARGE SURFACE AREA (1.8 SQUARE METERS) DIALYZER (ARTIFICIAL KIDNEY) BASED ON PROPRIETARY HOLLOW FIBER TECHNOLOGY. IN 1973 C-D BEGAN MARKETING A NEW AND EVEN MORE EFFICIENT 2.5 SQ. M. DIALYZER. THESE TWO LARGE SURFACE AREA DIALYZERS HAVE SIGNIFICANT ADVANTAGES OVER OTHER ARTIFICIAL KIDNEYS IN TERMS OF EFFICIENT REMOVAL OF BLOOD IMPURITIES AND CONTROL OF FLUID REMOVAL, THUS ALLOWING SHORT-TERM (LESS THAN 5 HOURS) DIALYSIS TO THE BENEFIT OF PATIENT REHABILITATION.

(2) BY 1977 C-D HAD ACHIEVED THE FIRST SUPPLIER POSITION IN THE JAPANESE DIALYZER MARKET (APPROXIMATELY 16 PERCENT UNCLASSIFIED

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OF THE MARKET WITH MONTHLY SALES OF ABOUT DOLLARS 1,200,000). ABOUT HALF OF ITS 1977 SALES, AND MOST OF EXPECTED FUTURE SALES INCREASES, WERE BASED ON THE NEWER 2.5 SQ. M. DIALYZER. C-D IS THE SOLE SUPPLIER OF 2.5 SQ. M. DIALYZER TO THE JAPANESE MARKET AND IS THE DOMINANT SUPPLIER OF SHORT-TERM DIALYZERS. NO OTHER SUPPLIER TO THE JAPANESE MARKET, FOREIGN OR DOMESTIC, PROVIDES A DIALYZER WITH SUCH A BROAD CAPABILITY.

(3) PRIOR TO FEBRUARY 1978, THE JAPANESE NATIONAL HEALTH INSURANCE SYSTEM FULLY COVERED ALL DIALYSIS EXPENSES BY 100 PERCENT REIMBURSEMENT OF THE INVOICE COST TO THE PROVIDER OF SERVICES (E.G. HOSPITALS). AS A CONTROL ON "RISING DIALYSIS COSTS", MHW ON FEBRUARY 1, 1978, ESTABLISHED A FUNDING SCREEN PROVIDING A MAXIMUM REIMBURSEMENT FOR TOTAL DIALYSIS SERVICES AND PRODUCTS. THE UNIQUE FEATURE OF THE NEW JAPANESE FUNDING PROGRAM IS THAT PAYMENT VARIES ACCORDING TO TIME SPENT ON DIALYSIS, AND SHORT-TERM DIALYSIS IS SEVERELY PENALIZED. PAYMENT FOR FIVE-NINE HOUR DIALYSIS, USING RELATIVELY LOW-COST DIALYZERS, IS SET AT YEN 40,000 WHEREAS PAYMENT FOR DIALYSIS IN LESS THAN FIVE HOURS IS SET AT YEN 30,000, DESPITE THE HIGHER COST OF THE MORE EFFICIENT DIALYZER. (DIALYSIS IN LESS THAN FIVE HOURS REPORTEDLY REPRESENTS ABOUT 20 PERCENT OF ALL JAPANESE DIALYSIS TREATMENTS.) THIS IS IN CONTRAST TO THE U.S. FUNDING SCREEN ADMINISTERED BY THE HEALTH CARE FINANCING ADMINISTRATION (HCFA) UNDER THE

DEPARTMENT OF HEALTH, EDUCATION AND WELFARE, WHICH SETS A MAXIMUM PAYMENT FOR TOTAL DIALYSIS TREATMENT, BUT DOES NOT

DISCRIMINATE ON THE BASIS OF TIME SPENT OR PRODUCT USED. TO BEST OF OUR KNOWLEDGE (BASED ON CONVERSATIONS WITH C-D, HCFA, AND NATIONAL INSTITUTES OF HEALTH), NO OTHER COUNTRY HAS A FUNDING SCREEN FOR DIALYSIS SIMILAR TO THAT OF JAPAN. HCFA OFFICIALS BELIEVE THE NEW JAPANESE PROCEDURE DISCRIMINATES AGAINST EFFICIENT SHORT-TERM DIALYZERS AND SEEMS UNCLASSIFIED

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CONTRARY TO THE INTERESTS OF PATIENTS WHO MIGHT BENEFIT FROM SHORTER DIALYSIS SESSIONS.

(4) THE RESULT OF JAPAN'S NEW FUNDING SCREEN HAS BEEN TO VIRTUALLY ELIMINATE C-D'S LARGE SURFACE AREA DIALYZERS FROM THE MARKET. TOTAL C-D DIALYZER SALES IN JAPAN DROPPED IN MARCH TO DOLLARS 390,000 FROM DOLLARS 1,200,000 IN DECEMBER OF 1977. MOST OF THIS REDUCTION COMES FROM THE SUDDEN LOSS OF SALES OF SHORT-TERM DIALYZERS SUCH AS THE 2.5 SQ. M. DIALYZER. SOME OF THE REDUCTION IS BASED ON PRICE-CUTTING OF ALL C-D DIALYZERS, BUT C-D STATES THAT IT CANNOT CUT PRICES ON SHORT-TERM DIALYZERS SUFFICIENTLY TO MAKE THEM COMPETITIVE UNDER THE NEW FUNDING SCREEN.

C. ARGUMENT:

(1) THE NEW JAPANESE GOVERNMENT FUNDING SCREEN DISCRIMINATES AGAINST SHORT-TERM DIALYSIS AND SHORT-TERM DIALYZERS, EXCLUDING THEREBY A MAJOR AMERICAN SUPPLIER FROM THE JAPANESE DIALYSIS MARKET. BY ITS ACTION MHW HAS FAVORED JAPANESE FIRMS WHICH HAD NOT HAD THE CAPABILITY TO EFFECTIVELY COMPETE WITH THE U.S. PRODUCT AND ITS SUPPLIER.

(2) PRIOR TO THE FEBRUARY 1, CHANGE, C-D WAS THE FIRST SUPPLIER IN THE JAPANESE DIALYZER MARKET, THE SOLE SUPPLIER OF THE LEADING SHORT-TERM DIALYZER (2.5 SQ. M.), AND THE DOMINANT SUPPLIER OF ALL TYPES OF SHORT-TERM DIALYZERS. THE NEW FUNDING PROCEDURE APPEARS TO BE BIASED AGAINST SUPPLIERS OF SHORT-TERM DIALYZERS SUCH AS C-D TO THE DETRIMENT OF U.S. EXPORTS.

(3) THE BASIS FOR THE MHW DECISION WAS TO CONTROL RISING UNCLASSIFIED

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DIALYSIS COSTS. WHILE THE OBJECTIVE IS WORTHY ITS APPLICATION APPEARS MISDIRECTED SINCE IT UNNECESSARILY AND UNFAIRLY PENALIZES EFFICIENT SHORT-TERM DIALYSIS. TO USG'S KNOWLEDGE NO OTHER COUNTRY IN THE WORLD HAS A SIMILAR

FUNDING SCREEN WHICH DISCRIMINATES ON THE BASIS OF TIME SPENT OR PRODUCT USED, ALTHOUGH MANY COUNTRIES SHARE THE OBJECTIVE OF CONTROLLING RISING DIALYSIS COSTS AND HAVE ESTABLISHED FUNDING SCREENS (I.E. MAXIMUM PAYMENTS).

(4) THE MANNER IN WHICH THE CHANGE WAS MADE AND ANNOUNCED HARMED THE AMERICAN SUPPLIER AND CREATES AN IMPRESSION THAT INSUFFICIENT CONSIDERATION WAS GIVEN TO THE EFFECT OF THE CHANGE ON JAPANESE IMPORTS. ACCORDING TO HCFA, ANY CHANGES IN THE U.S. SCREEN WOULD FALL UNDER FEDERAL ADMINISTRATIVE RULEMAKING PROCEDURES WHICH REQUIRE A 90-DAY PERIOD FOR PUBLIC COMMENT FOLLOWING ANNOUNCEMENT OF A PROPOSED CHANGE BEFORE SUCH A CHANGE CAN BE IMPLEMENTED. IN PRACTICE, IMPLEMENTATION USUALLY OCCURS THREE-SIX MONTHS AFTER THE END OF THIS PERIOD, PARTICULARLY IF THERE ARE PUBLIC HEARINGS. BY CONTRAST, C-D FIRST LEARNED OF THE PROPOSED JAPANESE CHANGE IN A JANUARY 12 JAPANESE NEWSPAPER ACCOUNT. THERE WAS THUS ALMOST NO ADVANCE NOTICE OF THE PROPOSED CHANGE, NO OPPORTUNITY TO COMMENT, AND NO PUBLIC HEARINGS.

(5) THE TIMING AND EFFECT OF THE NEW PROCEDURE WAS TO EXCLUDE, VIRTUALLY OVERNIGHT, A SUCCESSFUL U.S. EXPORTER FROM THE GROWING JAPANESE DIALYSIS MARKET AND PARTICULARLY THE SHORT-TERM DIALYSIS MARKET. THIS APPEARS TO DISCRIMINATE AGAINST THE U.S. EXPORTER TO THE ADVANTAGE OF DOMESTIC JAPANESE SUPPLIERS. FURTHERMORE, THE NEW JAPANESE PROCEDURE WOULD APPEAR TO REVERSE THE GROWTH IN SHORT-TERM DIALYSIS TREATMENTS TO THE DETRIMENT OF PRODUCT DEVELOPMENT AND PATIENT INTERESTS.

D. RELIEF SOUGHT:
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WE REQUEST ON BEHALF OF C-D THAT MHW IMMEDIATELY REVISE ITS FUNDING SCREEN FOR DIALYSIS REIMBURSEMENT TO SET THE SAME PAYMENT FOR SHORT-TERM DIALYSIS AS FOR FIVE-NINE HOUR DIALYSIS, I.E. YEN 40,000, SO AS NOT TO DISCRIMINATE ON THE BASIS OF TIME SPENT OR PRODUCT USED IN DIALYSIS. ANY

CHANGE IN THE JAPANESE FUNDING PROGRAM MUST COME QUICKLY IF C-D'S LARGE SURFACE AREA DIALYZER AND TOTAL DIALYZER SALES IN JAPAN ARE NOT TO BE IRREPARABLY DAMAGED. END TEXT.

4. EMBASSY MAY USE FOLLOWING TALKING POINTS IN DISCUSSIONS OF CASE WITH MHW AND JAPANESE TFC OFFICIALS: (1) THE ACTUAL EFFECT OF THE NEW FUNDING SCREEN WOULD APPEAR TO BE TO SEVERELY DEPRESS SHORT-TERM DIALYSIS IN JAPAN AS A PROPORTION OF TOTAL DIALYSIS TREATMENTS, C-D ESTIMATES THIS PROPORTION IS ALREADY FALLING FROM ABOUT TWENTY PERCENT TO LESS THAN ONE PERCENT. AS A PRACTICAL

MATTER, THERE SHOULD BE A TENDENCY FOR REPORTED DIALYSIS TO TAKE SLIGHTLY MORE THAN FIVE HOURS FOR AN EXTRA YEN 10,000 RATHER THAN SLIGHTLY LESS THAN FIVE HOURS. DOES

MHW HAVE ESTIMATES AND PROJECTIONS OF THE PROPORTIONS OF SHORT-TERM DIALYSIS PRIOR TO THE FEBRUARY 1 CHANGE AND CONSEQUENT TO IT? HOW CAN "OVER-DIALYSIS" OR "OVER-REPORTING" OF TIME SPENT ON DIALYSIS BE AVOIDED UNDER THE NEW SYSTEM?; (2) THE DIFFERENCE BETWEEN THE YEN 40,000 PAYMENT FOR FIVE-NINE HOUR DIALYSIS AND YEN 30,000 PAYMENT FOR LESS THAN FIVE HOUR DIALYSIS IS PARTIALLY EXPLAINABLE BY LABOR COSTS; ON THE OTHER HAND, HIGHER EQUIPMENT COSTS (HIGHER COST OF SHORT-TERM DIALYZER), AS WELL PERHAPS AS BETTER UTILIZATION OF LABOR AND PATIENT UNCLASSIFIED

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TIME, WOULD APPEAR TO JUSTIFY A HIGHER PAYMENT FOR SHORT-TERM DIALYSIS DESPITE LOWER LABOR COSTS. WHILE THE EXACT TRADE-OFF IN THE CASE OF JAPAN IS PERHAPS DEBATABLE, THE DIALYSIS SCREENS OF THE UNITED STATES AND OTHER COUNTRIES, WHICH DO NOT DISCRIMINATE ON BASIS OF TIME SPENT OR PRODUCT USED, ARGUE IN FAVOR OF EQUAL PAYMENT PER DIALYSIS AND LEAVING THE TRADE-OFF BETWEEN LABOR COSTS AND EQUIPMENT COSTS/BETTER UTILIZATION TO THE PRIVATE SECTOR; (3) (TO BE RAISED ONLY IF MHW BROACHES SUBJECT) AS INDICATED IN C-D BRIEF, THE CHANGE IN REIMBURSEMENT PROCEDURES APPEARS TO FAVOR JAPANESE PRODUCERS WHICH ARE ENTERING THE MARKET AND EXPANDING CAPACITY FOR DIALYZERS WHICH COULD NOT FULLY COMPETE WITH C-D'S LARGE SURFACE AREA, HOLLOW FIBER, SHORT-TERM DIALYZERS PRIOR TO THE CHANGE. THUS, THE REVISED PROCEDURE, ALTHOUGH IT MAY ONLY BE TEMPORARY, MAY IN EFFECT AID JAPANESE COMPETITORS OF C-D NOT ONLY IN THE JAPANESE MARKET BUT IN MOUNTING AN EXPORT DRIVE TO OTHER COUNTRIES, INCLUDING THE UNITED STATES; (4) AS A GENERAL OBSERVATION, FUTURE CHANGES IN MHW AND OTHER JAPANESE GOVERNMENT PRACTICES AND PROCEDURES WHICH MAY SIGNIFICANTLY AFFECT JAPANESE IMPORTS COULD BE NOTIFIED TO THE PUBLIC WITH REASONABLE ADVANCE AND OPEN TO PUBLIC COMMENT INSOFAR AS POSSIBLE. TFC CONSIDERATION OF PROPOSED CHANGES PRIOR TO COMMITMENT BY A GOJ AGENCY TO ADOPT THEM OR PRIOR TO THEIR ACTUAL IMPLEMENTATION WOULD NATURALLY ENHANCE THE PROSPECT FOR FAVORABLE RESOLUTION AND THE AVOIDANCE OF TRADE DAMAGE.

5. C-D SUGGESTS THAT EMBASSY CONTACT H. WATANABE, C-D MANAGER FOR MARKETING AND ADMINISTRATION AT 2-12-604 SHIMO-OTSUKI, HATANO, KANAGAWA 257 (TEL. 0463-77-4413) FOR COPY OF NEW MHW REGULATIONS AND OTHER INFORMATION CONCERNING PRICES AND COSTS IN SUPPORT OF ABOVE TALKING POINTS. IN ADDITION, EMBASSY SHOULD CONTACT Y. SONADA, PRESIDENT OF HOME PATIENTS UNION, AT 2-309, 29-BAN, 4-CHOME, KAMISHINDEN, TOYONAKA CITY, OSAKA (TEL. AFTER

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5 P.M. 06-833-5299) FOR VIEW THAT NEW MHW PROCEDURE IS
CONTRARY TO BEST INTERESTS OF SELF-DIALYZING PATIENTS.

6. ACTION REQUESTED: EMBASSY IS REQUESTED TO SUBMIT ABOVE
CASE TO TFC (MHW) SOONEST, UNLESS EMBASSY IS AWARE OF IN-
FORMATION CONTRARY TO FACTS AS REPRESENTED. TIME IS OF
THE ESSENCE IF FURTHER DAMAGE TO C-D MARKET POSITION AND
U.S. EXPORTS IS TO BE AVOIDED. VANCE

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